

Role of Laparoscopic Splenectomy in Isolated High-Grades Splenic Injuries: A Randomized Controlled Trial

Tamer A.A.M. Habeeb*, Emad Salah, Ahmed S. Mohamed , Said M. Negm

Department of General Surgery, Faculty of Medicine, Zagazig University, Egypt

ABSTRACT

Background: Spleen is the most common intra-abdominal organ injury in blunt abdominal trauma. Splenectomy (open or laparoscopic) plays a role in the treatment of severe injuries of spleen or after the failure of conservative treatment.

Aim of the work: to compare the outcomes between open versus laparoscopic splenectomy in high-grade splenic injuries (Grades III-IV).

Methods: This study includes 70 patients with various grades of splenic injuries in abdominal trauma. The patients were 15 years and older. They were categorized into two groups: open splenectomy group (35 patients) and laparoscopic splenectomy group (35 patients). This study was performed from January 2012 to July 2017. Variables included demographic data, splenic injury graded by computerized tomography, duration of operation (in minutes), intra-operative blood loss (in ml), and intraoperative blood transfusion, length of hospital stay (in days), complications and mortality.

Results: There was no significant difference or association between groups as regards age, sex and causes of splenic injury ($p=0.374, 0.41, 0.38$). Most cases were under-35-year-old male patients exposed to motor car accidents. As regards intraoperative data, there was no statistically significant difference between both groups, except for blood loss and transfusion which were statistically significant to the open group ($p=0.039^*$). In the laparoscopic group, operational time was longer than that in the open group, but there was no statistically significant ($p=0.11$) difference. As regards conversion, we found that 14% of the laparoscopic group (5 cases) had conversion. Most cases operated by laparoscopic approach were in grade III, IV with no cases tried in grade V ($p=0.06$). There was no statistically significant difference between both groups as regards postoperative variables, except pain ($p=0.0003$) and hospital stay ($p=0.00$) which were significantly longer in the open group. The immediate postoperative complications showed that wound infection, missed injuries, pancreatic fistula and ileus were significantly higher in the open group ($p=0.00, 0.006, 0.02, 0.0004$). The delayed postoperative complications which were incisional hernia ($p=0.001$) and adhesive intestinal obstruction ($p=0.00$) were significantly associated with the open group.

Conclusion: For patients of high-grade splenic injuries, this study found that laparoscopic splenectomy is safe.

Key words: laparoscopy, non-penetrating, splenectomy

*Corresponding author:

Tamer Alsaied Alnaimy
Assistant Professor of General Surgery
Department of General Surgery
Faculty of Medicine
Zagazig University, Egypt
E-mail: tameralnaimy@hotmail.com

HIGHLIGHTS:

- Blood loss and blood transfusion were statistically significant to the open group.
- Postoperative pain and hospital stay were significantly longer in the open group.
- Immediate postoperative complications showed that wound infection, missed injuries, pancreatic fistula, and ileus were significantly higher in the open group.
- Delayed postoperative complications were incisional hernia and adhesive intestinal obstruction and they were significantly associated with the open group.

Abbreviations:

CT: computed tomography scanning,
Vs: versus,
Lap: laparoscopic.

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INTRODUCTION

Ruptured spleen is the commonest incidence of trauma to the abdomen,

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especially to the left hypochondrium. The commonest cause is road traffic accidents (1-2). Spleen may be injured either separately or with other nearby organs such as kidney, bowel and ribs. Ruptured spleen is suspected in poly-traumatized patients and is usually associated with decreased blood pressure and increased heart rate (3-5).

Different methods are developed, aiming at the grading of splenic trauma, and this classification helped with different methods of treating splenic injuries. CT (Computerized Tomography) grading is important and the splenic injuries are classified into five grades, according to the severity of splenic injuries (6-10).

Laparoscopic total splenectomy for splenic injuries was performed in 1995 in hemodynamically stable patients (11). Laparoscopic splenectomy is avoided in hemodynamically unstable patients or severe cases of splenic injuries with continuous severe bleeding as delay in time to intervention may endanger the patient's life (12).

Laparoscopy put the open approach aside because of small operative wound and brought about better cosmesis and less postoperative pain and infection. Laparoscopy also gives a panoramic view of the whole abdomen and this helps not to miss associated injuries (13).

There are few studies handling laparoscopic splenectomy in high-grade injuries.

Research question: is laparoscopic splenectomy safe in a high-grade splenic injury?

Hypothesis: laparoscopic splenectomy is safe in a high-grade splenic injury.

The aim of the work and strength of the study:

High-grade splenic injuries necessitate urgent splenectomy and are usually conducted by open approach due to rapid approach and no experienced laparoscopic splenectomy surgeons for trauma. Few studies were conducted on the treatment of splenic injuries using laparoscopic approach, but we conducted a randomized controlled clinical study on these types of injuries, including high-grade injuries. The role of laparoscopy has been evolving in the last decades, but its role in dealing with traumatic spleen is a matter of debate. The main aim was to compare open splenectomy and laparoscopic splenectomy in high-grade splenic injuries (III-IV) in hemodynamically stable patients regarding intraoperative and postoperative parameters. The secondary aim was to determine the role of laparoscopy in splenic trauma as having an

actual role (fact) or whether it is not supposed to be used (myth).

PATIENTS AND METHODS

The design of the study

Prospective randomized clinical study was conducted in our University Hospital emergency surgery unit between Jan 2012 and July 2017 for 70 patients admitted to high-grade splenic injuries (III-V). The patients were randomly allocated into two groups: Group (A): includes 35 patients who underwent open splenectomy and Group (B): includes 35 patients who underwent laparoscopic splenectomy. The method for calculating sample size was based on mortality rates from previous papers with a study power of 80 and confidence of 95 samples in each group will be 35. Patients were randomly allocated using a random sequence computer. Patients were randomly numbered in closed envelopes, which were opened just before the operation. Patients were unaware of the group to which they belonged until after the study. It was the role of the registration office to ensure this.

Patient selection criteria

Patients enrolled in the study are male and non-pregnant female, age 15 years and more, preoperative sonar and CT evidence of isolated splenic injuries and blood pressure > 90/60 mmHg, and heart rate < 120 beats. Patients excluded from the study were patients with other associated systems or intra-abdominal injuries, successful non-operative management, or successful embolization and penetrating splenic injuries.

Types of outcome and measurement (study endpoints)

The outcomes were intraoperative and postoperative parameters as regards postoperative pain (on visual analogue score), length of surgery (in minutes), intraoperative blood loss (ml), duration of hospital admission (in days), wound infection at any time, missed injuries, incisional hernia and adhesive intestinal obstruction.

METHOD

Preoperative workup was done by focused assessed sonography for trauma (FAST) and CT of the abdomen.

All patients in the present study were subjected to immediate initial resuscitation and primary survey, followed by secondary survey and routine laboratory investigations. After resuscitation and stabilization of the vital signs, abdominal ultrasonography and computed tomography scans were carried out for all cases (*figure 1*). Preoperative consultant anesthetist's assessment; Nasogastric tube and urinary bladder catheter: With the induction of anesthesia, metronidazole 500 mg and ceftriaxone 1gm were given intravenously. There was general anesthesia with cuffed endotracheal intubation. All surgeries were done in mono-center in trauma surgery unit for a duration of 5 years by 3 surgeons qualified in laparoscopic splenectomy surgery following the principles of laparoscopic surgery. Each surgeon had experience of previous 100 laparoscopic splenectomies for elective cases. At least one of three senior surgeons was always present to ensure inclusion criteria.

A laparoscope of 30° was inserted following induction of pneumoperitoneum (12 mm Hg) with a Veress needle, and a massive hemoperitoneum was visualized and aspirated by a suction irrigation device. Three additional trocars, left side to umbilical port for the surgeon, and third left side for the assistant, were laid in the epigastrium. Careful abdominal cavity inspection confirmed the spleen was the sole source of bleeding (*figure 2*). The spleno-colic ligament was broken downwards. By harmonic scalpel, the shorts of the gastric vessels and the attachments in the lower polar were divided. The splenic artery was prepared and ligated, then cut. It was assured that the pancreatic tail was not damaged (*figures 3, 4*). The lateral attachments were divided to allow splenic mobilizations. With a 3-cm incision and through endobag, the spleen was removed (*figure 7*). Extensive uncontrolled bleeding is an indication of laparotomy (*figures 5, 6*).

Postoperatively, fluid was allowed as tolerated when the patients had open bowel. Antibiotics were continued for 5 days. A drain was removed when it contained less than 50 C.C for 3 days. Vaccination occurred after 2 weeks of postoperative surgery. The follow-up period was one month, six months, twelve months and 18 months after returning home. After returning home, patients were contacted by mail, telephone and at an outpatient clinic. Techniques of follow-up included complete history and physical examination to detect remote complications and ultrasonography if patients are symptomatising in the follow-up period. No cases were lost in the follow-up period.

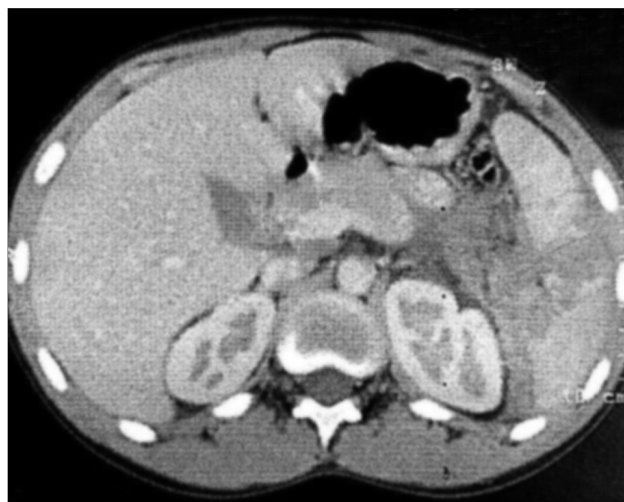


Figure 1 - CT shows grade IV splenic injury

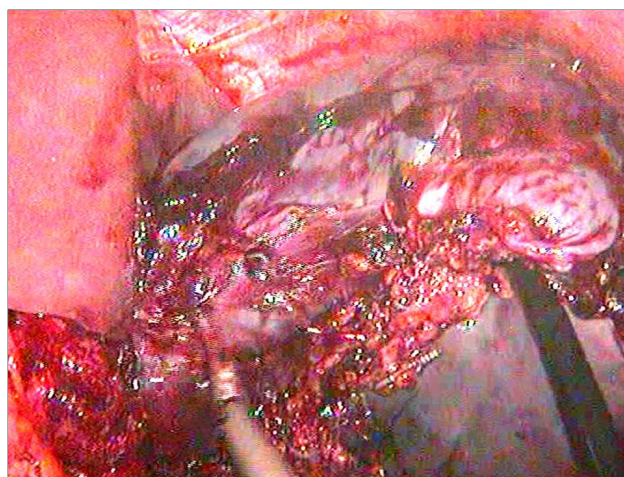


Figure 2 - Laparoscopic view showing lacerated spleen

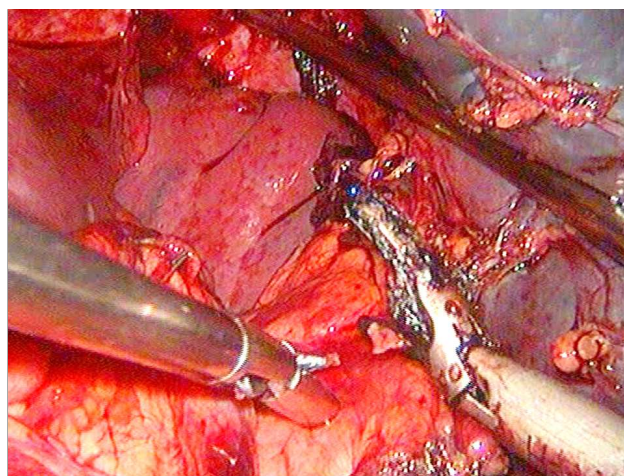


Figure 3 - Dissection of hilum of spleen with care to pancreas

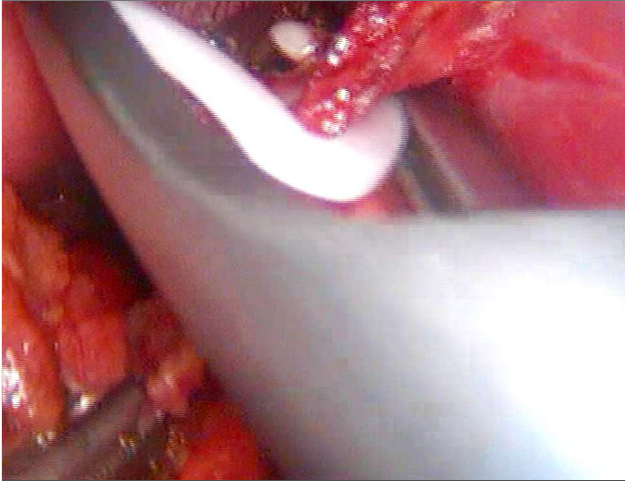


Figure 4 - Ligation of the hilar vessel with hemoclip

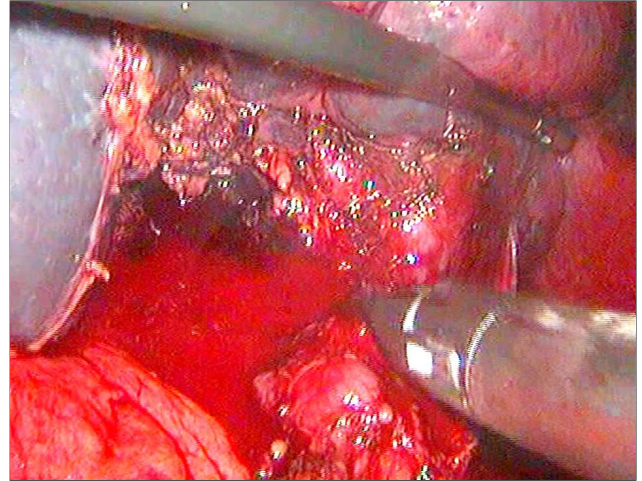


Figure 5 - The first case converted to open approach due to uncontrolled bleeding from the hilum

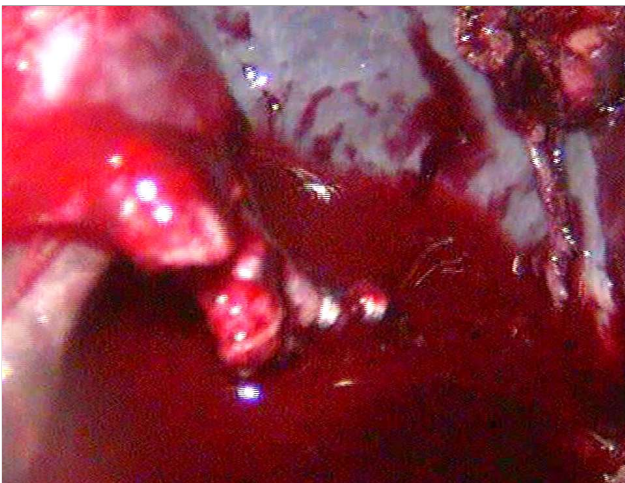


Figure 6 - The 2nd case converted to open approach due to uncontrolled bleeding from the hilum

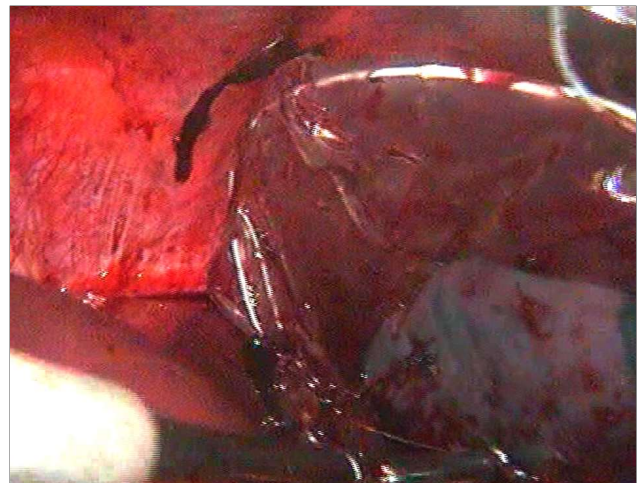


Figure 7 - The spleen is enclosed inside endobag

Statistical analysis

The data were imported into the Social Sciences Statistical Package (SPSS version 20.0). The following tests were used for testing of difference of significance, depending upon the type of data qualitative as number and percentage quantitative continuous group represented by average \pm SD, and Chi-square test differential and associate qualitative variable (χ^2). There were differences between quantitative independent groups by t-test or Mann Whitney, for significant results. P value was set at < 0.05 & < 0.001 for high significant results.

RESULTS

There was no statistically significant difference or

association between groups as regards age, sex and causes of splenic injury ($p=0.374, 0.41, 0.38$). Most cases were under-35-year old male patients exposed to motor car accidents (*table 1*). As regards intraoperative data, there was no statistically significant difference between both groups except for blood loss and transfusion which were statistically significant to the open group ($p=0.039^*$). In the laparoscopic group, operational time was longer than that in the open group but there was no statistically significant ($p=0.11$) difference. As regards conversion, we found that 14% of the laparoscopic group (5 cases) had conversion. Most cases operated by laparoscopic approach were in grade III, IV with no cases tried in grade V ($p=0.06$) (*table 2*). There was statistically significant difference between both groups as regards postoperative variables except

Table 1 - Demographic data

	Open splenectomy (35 cases)	Laparoscopic splenectomy (35 cases)	χ^2	P
Age				
15-25	5 (14.3%)	7 (20%)	4.19	0.21
26-35	22 (62.8%)	24 (68.5%)		
36-45	6 (17.2%)	1 (2.8%)		
>45	2 (5.7%)	3 (8.7%)		
	34.58±10.58	33.41±11.02	t=0.84	0.374
Sex				
male	25 (71.4%)	28 (80%)	0.69	0.41
female	10 (28.6%)	7 (20%)		
Cause of abdominal trauma				
motor car accident	28 (80%)	27 (77.1%)	0.71	0.38
blow to the abdomen	3 (8.7%)	2 (5.7%)		
falling from a height	4 (11.3%)	6 (17.2%)		

There was no significant difference or association between groups

Table 2 - Intraoperative data

	Open splenectomy (35 cases)	Laparoscopic splenectomy (35 cases)	χ^2	P
Operative time				
< 60 minutes	8 (22.9%)	3 (8.7%)	0.269	0.11
>60 minutes	27 (77.1%)	32 (91.3%)		
Blood loss(ml)				
500 ml	7 (20%)	15 (42.8%)	4.21	0.039*
>500 ml	28 (80%)	20 (57.2%)		
Blood transfusion (unit)				
one unit	7 (20%)	15 (42.8%)	4.21	0.039*
≥ 2 units	28 (80%)	20 (57.2%)		
Grade of splenic injuries				
Grade III	22 (62.9%)	25 (71.4%)	5.41	0.06
Grade IV	8 (22.9%)	10 (28.6%)		
Grade V	5 (14.2%)	0 (0.00%)		
Conversion	0 (0.0%)	5 (14%)	12.07	0.0005**

Blood loss and blood transfusion were significantly associated with open group, regard conversion we found that 14.2% of laparoscopic group (5 cases) had conversion

pain (p=0.0003) and hospital stay (p=0.00) which were significantly longer in the open group. The immediate postoperative complications showed that wound infection, missed injuries, pancreatic fistula and ileus were significantly higher in the open group (p=0.00, 0.006, 0.02, 0.0004). The delayed postoperative complications which were incisional hernia (p=0.001) and adhesive intestinal obstruction (p=0.00) were significantly associated with the open group (table 3).

DISCUSSION

This study compared the open approach with the laparoscopic approach in high-grade splenic injuries. We concluded that the laparoscopic approach is less in intraoperative blood loss and hence blood transfusion, but operative time is longer in the open approach and

the conversion rate reaches 15% of cases. The post-operative outcomes regarding local wound complications, immediate and delayed postoperative complications are less in the laparoscopic approach than in the open approach.

Changes in surgical approach evolved in the last decade, secondary to the urging of technology. Studies were performed on grade III splenic injuries and stated that the operative time is longer in laparoscopic splenectomy than the open approach. The studies also stated that there was no difference in morbidity and mortality between both approaches and that laparoscopic splenectomy is a safe approach (14-15). The present study agrees with the previous studies as regards operative time but does not agree with them regarding morbidity and mortality as our study showed superiority of the laparoscopic approach as regards

Table 3 - Postoperative data

	Open splenectomy (35 cases)	Laparoscopic splenectomy (35 cases)	χ^2	P
Postoperative pain				
< 2 days	12 (34.2%)	27 (77.1%)	13.12	0.0003**
> 2 days	23 (65.8%)	8 (22.9%)		
Postoperative analgesic				
< 1 week	18 (51%)	25 (71%)	2.95	0.08
>1week	17 (48%)	10 (28%)		
Postoperative hospital stay				
< 5 days	7 (20%)	25 (71%)	18.66	0.00**
> 5 days	28 (80%)	10 (28%)		
ICU admission (days)				
1-3 days	30 (85.8%)	32 (91.6%)	0.59	0.74
4-7 days	3 (8.5%)	2 (5.7%)		
> 7 days	2 (5.7%)	1 (2.7%)		
Wound infection	15 (42.8%)	2 (5.7%)	28.11	0.00**
Missed injuries	5 (14.2%)	1 (2.8%)	7.42	0.006*
Pancreatic fistula	4 (11.4%)	1 (2.8%)	5.23	0.02*
Incisional hernia	6 (17.1%)	1 (2.8%)	10.11	0.001**
Adhesive intestinal obstruction	8 (22.8%)	0	20.88	0.00**
OPSI	0	0	0.0	1.0

Pain significantly stays more among open group also post-operative hospital stay was significantly longer among open group. Wound infection, Missed injuries, pancreatic fistula and ileus were significantly higher among open group. Incisional hernia and Adhesive intestinal obstruction were significantly associated with open group

**Strongly significant

postoperative complications. Longer intraoperative laparoscopic time is attributed to time taken for the introduction of trocars and laparoscopic instruments. Additional factors to increase operative time are masking the telescope with blood and the time is needed to clean the telescope outside the abdomen. Minimal intraoperative bleeding was due to the panoramic view which helped us in controlling the bleeding site and thanks to the Harmonic scalpel instrument. All these factors helped to diminish the need for blood transfusion in the laparoscopic approach. New technologies provided a special excellent instrument as harmonic scalpel and ligasure that are excellent tools in hemostasis during the surgery and the operation must be performed after the availability of these tools (16). In the present study, the harmonic scalpel allowed us to dissect the short gastric vessels, especially the ligamentous attachments of the lower poles of the spleen and hence decrease operative time and bleeding.

Conversion to open occurred in 5 cases (14%) due to failure to control bleeding during the operation. Three cases are converted in the first few minutes of operation due to inability to control bleeding and the last two cases are converted during dissection of the hilum of the spleen with sudden uncontrolled bleeding.

A panoramic view of the abdomen by laparoscopy

helps to detect associated injuries and avoid missed injuries that may reach up to 18% of cases (17). In our study; the missed injuries were high in the open group than the laparoscopic group (14% vs. 3%) and mostly due to missed injury of the pancreatic tail. Cases presented with intra-abdominal abscess and pain with fever. 4 cases of missed injuries in the open group and one missed case in the laparoscopic group were due to missed pancreatic tail injuries. All of them were grade B fistula and were treated successfully by percutaneous drainage under ultrasonography guidance, nothing per oris, metronidazole 500 mg injection and third-generation cephalosporin. No cases needed re-exploration. While the fifth missed case of the open group was due to colonic injuries, abdominal pain and fever were diagnosed 5 days post-operation and underwent re-exploration and temporarily simple loop colostomy that was closed 8 weeks after.

Among the advantages of laparoscopy over open approach are small operative wounds and hence pain and infection. Rapid resumption of oral feeding and rapid return to works are also advantages (18). The present study confirmed the importance of laparoscopy in less postoperative pain, less duration of analgesic intake and shorter hospital stay in the laparoscopic approach than the open approach.

Postoperative wound infection is related to the size

of the wound. In the present study, we concluded that 15 cases (43%) in the open approach and 2 cases (6%) in the laparoscopic approach were complicated by wound infection. All cases were treated according to culture and sensitivity with local wound drainage and antibiotic injection.

OPSI is the most fatal complication after splenectomy. After splenectomy, the antibodies are preserved but there is a loss of memory B cells monocytes responsible for attacking capsulated bacteria that are the most virulent pathogens in these patients. Vaccination with polyvalent vaccines against *Streptococcus pneumoniae*, *Haemophilus influenzae*, and *Neisseria meningitidis* should be performed before the splenectomy to decrease the incidence of OPSI. Overwhelming post-splenectomy (OPSI) infection incidence may be up to 2%. Infection occurred by capsulated bacteria and it is usually fatal in 70% of cases who complained of this problem (19). Post-splenectomy vaccinations against the causative agents are available and are given after 2 weeks of operation. 23-valent pneumococcal polysaccharide vaccine (PNEUMOVAX 23) is usually given after surgery and repeated two years later (20). In the present study, no cases developed OPSI as all cases received polyvalent vaccines within 2 weeks after splenectomy and every 5 years until 25 years old.

CONCLUSIONS

Our results concluded that intraoperative and postoperative immediate and delayed complications are less in the laparoscopic approach than the open approach. Laparoscopic splenectomy may be performed safely in the presence of experienced surgeons using modern ligasure apparatus and anesthesiologists. So, we recommend a laparoscopic approach in blunt abdominal trauma even in high grades (Grade III, IV).

Limitations of this study

The role of laparoscopy in splenic trauma is needed to perform on a larger number of cases. Another limitation we faced in this study is the availability of an experienced anesthesia team to control the hemo-dynamicality of the patients in emergency units all the time. Also, another limitation was the short follow-up period for the last cases to detect adhesive intestinal obstruction and OPSI. (1.5 years). Further studies are needed to handle grade V splenic injuries.

Contributions of the authors

All the authors shared important intellectual content in the study design, data analysis, and written and critical revision. The version they submitted was shared in their final approval.

Conflict of interest

All author declare that they have no conflict of interest.

Ethics approval, consent to participate

Faculty of Medical Ethical Committee Zagazig University gave us all the ethical agreements.

The described work has been carried out for human experiments under the World Medical Association's Code of Ethics (Helsinki Declaration).

The work has been reported in line with consolidated standards of reporting trials (CONSORT) guidelines.

Availability of data and materials: will be available on demand.

The Registration Registered quality control review criteria for clinicaltrials.gov protocol: NCT04329845 registered retrospective on 31 March 2020.

Consent for publication

After the study was included, all involved persons gave their informed written consent for publication.

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